K001785

510(K) SUMMARY

DEC 27 2000

Submitted By:

Neal E. Fearnot, Ph.D.
President
Cook Biotech Incorporated
3055 Kent Avenue
West Lafayette, IN 47906
(765) 497-3355
May 30, 2000

Names of Device:

Trade Name:	SURGISIS™ Peripheral Vascular Patch
Common/Usual Name:	Vascular Patch
Proposed Classification Name:	Intracardiac Patch or Pledget (21 CFR '870.3470)

Intended Use:

The SURGISIS™ Peripheral Vascular Patch is intended for implantation for peripheral vascular reconstruction, including the carotid, renal, iliac, femoral, and tibial blood vessels, arteriovenous access revisions, and suture line buttressing. The device is intended for one-time use.

Predicate Devices:

SURGISIS™ Mesh (K980431) manufactured by Cook Biotech Incorporated

Vascu-Guard Peripheral Vascular Patch and CV Peri-Guard™ Cardiovascular Patch (K983602) manufactured by Bio-Vascular, Incorporated

Device Description:

The Surgisis™ Peripheral Vascular Patch is manufactured from porcine small intestinal submucosa and is supplied in sheet form in sizes ranging from 2 cm^2 to 250 cm^2. The device is packaged in sterile, sealed double pouches.

Substantial Equivalence:

The Surgisis™ Peripheral Vascular Patch is substantially equivalent to the predicate devices, having similar intended use and technological characteristics. The substantially equivalent determination under the Federal Food, Drug, and Cosmetic Act is not intended to have any bearing whatsoever on the resolution of patent infringement suits or other patent matters.

Discussion of Tests and Test Results:

The Surgisis™ Peripheral Vascular Patch was subjected to a panel of tests to assess biocompatibility, integrity, and performance as measured by suture retention strength, ultimate tensile strength, probe burst strength, and suture hole elongation. The Surgisis™ Peripheral Vascular Patch passed the requirements of all tests, providing reasonable assurance of device performance for its intended use and supporting substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 27 2000

Neal E. Fearnot, Ph.D.
Cook Biotech Incorporated
3055 Kent Avenue
West Lafayette, IN 47906

Re: K001785
Trade Name: SURGISIS™ Peripheral Vascular Patch
Regulatory Class: II (two)
Product Code: DXZ
Dated: September 27, 2000
Received: September 28, 2000

Dear Dr. Fearnot:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial

equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K001785

Device Name: Cook Biotech, Inc. SurgiSIS™ Peripheral Vascular Patch

Indications For Use: for peripheral vascular reconstruction, including the carotid, renal, iliac, femoral, and tibial blood vessels, arteriovenous access revisions, and suture line buttressing.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K001785

(Optional Format 3-10-98)